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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,903	07/10/2001	Avi Ashkenazi	10466/69	1524

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EXAMINER	
BUNNER, BRIDGET E	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 10/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/902,903	ASHKENAZI ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendments of 10 July 2001 (Paper No. 1.5), 10 July 2001 (Paper No. 2.5), and 27 August 2002 (Paper No. 10) have been entered in full. Claims 1-38 are cancelled and claims 39-44 are added.

Claims 39-44 are under consideration in the instant application.

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

(a) Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

(b) It does not identify the citizenship of each inventor.

Specification

2. The disclosure is objected to because of the following informalities:

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (See pg 71, line 28; pg 154, line 17; pg 167, line 38; pg 178, line 34). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Appropriate correction is required.

Claim Rejections - 35 USC § 101 and 35 USC § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 39-44 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility. Novel biological molecules lack well established utility and must undergo extensive experimentation.

Specifically, claims 39-44 are directed to an antibody that binds to the polypeptide shown in Figure 86 (SEQ ID NO: 245). The claims also recite that the antibody is monoclonal or humanized. The claims recite that the antibody is an antibody fragment or that the antibody is labeled. However, the instant specification does not teach any significance or functional characteristics of the PRO293 (SEQ ID NO: 245) polypeptide or antibody. The specification also does not disclose any specific methods or working examples for the production of the antibody or labeling of the antibody. Since the utility is not presented in mature form and significant further research is required, the utility is not substantial. The specification asserts the following as patentable utilities for the claimed putative antibody against PRO293 (SEQ ID NO: 245):

1) to detect PRO293 polypeptide expression in specific cells, tissues, or serum (pg 146, lines 33-34)

2) as a therapeutic for treatment of various disorders (pg 145, lines 33-35)

3) for purification of PRO293 from recombinant cell culture or natural sources (pg 147, lines 7-8)

Each of these shall be addressed in turn.

1) to detect PRO293 polypeptide expression in specific cells, tissues, or serum. This asserted utility is credible but not substantial or specific. Such assays can be performed with any antibody. Further, the specification discloses nothing specific or substantial for the PRO293 polypeptide detected by this method. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

2) as a therapeutic for treatment of various disorders. This asserted utility is not credible, substantial, or specific. Such assays can be performed with any antibody. The specification discloses nothing about the normal level of expression of the PRO293 polypeptide. The specification does not disclose any disorders which are associated with altered levels or forms of the PRO293 polypeptide. Significant further experimentation would be required of the skilled artisan to identify individuals with such a disease. Since this asserted utility is also not presented in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

3) for purification of PRO293 from recombinant cell culture or natural sources. This asserted utility is credible but not substantial or specific. Such assays can be performed with any antibody. Further, the specification discloses nothing specific or substantial for the PRO293 polypeptide purified by this method. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

6. Claims 39-44 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

7. It is noted to Applicant that Examples 70 and 71 on page 207 of the specification also do not provide a usable activity of the PRO293 antibody to establish a credible, specific, and substantial asserted utility or a well established utility or enablement. The asserted utility of Example 70, PDB12 cell inhibition, is not credible, specific or substantial. The specification teaches that "a percent decrease in protein production of greater than or equal to 25% as compared to the negative control cells is considered positive" (pg 207, lines 16-17). However, any slight decrease in protein production, which may even result from the normal variations in cell number, would not indicate that PRO293 specifically inhibits protein production in PDB12 pancreatic ductal cells. Although the specification teaches that PRO293 is positive in this assay, the specification does not disclose any specific resulting cell numbers or percentages, statistical differences, or the number of repetitions for the assay. Without this knowledge, which could not be gleaned from the instant specification, one of ordinary skill in the art at the time the invention was made would not have been able to use the information obtained from this assay in a useful manner. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial. Antibodies can be made to any polypeptide. However, if the specification discloses nothing specific and substantial about the polypeptide, therefore both polypeptide and their antibodies have no patentable utility.

Furthermore, the asserted utility of Example 71, the stimulation of adult heart hypertrophy, is not credible, specific, or substantial. The specification teaches that "any degree of growth enhancement as compared to the negative control cells is considered positive for the assay" (pg 207, lines 30-31). However, any slight increase in cell growth, which may even result from the normal variations of the cell media, would not indicate that PRO293 specifically enhances myocyte cell growth. Although the specification teaches that PRO293 is positive in this assay, the specification does not disclose any specific resulting cell numbers, statistical differences, or the number of repetitions for the growth assay. The specification also does not teach what type of "cell growth" is measured in the assay (i.e., cell proliferation, cell differentiation). Without this knowledge, which could not be gleaned from the instant specification, one of ordinary skill in the art at the time the invention was made would not have been able to use the information obtained from this assay in a useful manner. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial. Again, antibodies can be made to any polypeptide. However, if the specification discloses nothing specific and substantial about the polypeptide, therefore both polypeptide and their antibodies have no patentable utility.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 39-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 39-44 are rejected as being indefinite because the difference between "an antibody that binds to the polypeptide" as recited in claim 39 and "an antibody which specifically binds to the polypeptide" as recited in claim 44 cannot be determined, absent a definition of "specific binding". It is not clear what each claim is meant to encompass, given that antibody binding is determined by the variable region structure and is a "specific" event.

Conclusion

No claims are allowable.

The art made of record and not relied upon is considered pertinent to applicant's disclosure:

Kobe et al. Trends in Biochem Sci 19(10): 415-421, 1994.

Hayata et al. Gene 221 : 159-166, 1998.

Taguchi et al. Mol Brain Res 35(1-2) 31-40, 1996.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:30-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 872-9305.

BEB
Art Unit 1647
September 25, 2002

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER